

III. REMARKS

Election/Restrictions

The examiner has required restriction under 35 U.S.C. 121 and 372 because the examiner believes this application contains inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The examiner has grouped the claims into two groups:

Group I, claims 1-6 and 11, drawn to methods for detection of cancers using primers of genes for APC, K-ras, β -catenin, or B-raf.

Group II, claims 7 and 9, drawn to primers and kits of primers of genes for APC, K-ras, β -catenin, or B-raf.

The examiner states that the special technical feature linking Groups I-II appears to be that they all relate to methods of detecting cancer using primers of genes for APC, K-ras, β -catenin or B-raf and goes on to state that Salahsor et al. (1999) teach a process for early detection of colorectal cancer, which is based on the PCR analysis of the APC gene, the K-ras gene and the β -catenin gene (abstract, page 248, column 2, paragraph 2). The genes are known to contain a plurality of potential mutational sites associated with the development of cancer.

Therefore, the examiner concludes that the technical feature linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Applicant respectfully disagrees.

The examiner has misread applicants claims. Applicant's claims do not require relate to methods of detecting cancer using

primers of genes for APC, K-ras, β -catenin or B-raf. Applicant's claims relate to methods of detecting cancer using primers of genes for APC, K-ras, β -catenin and B-raf.

The crux of applicant's invention and claims is that four genes are required and that the four genes are those specified. The examiner has not cited any reference that discloses or suggests the necessity for using primers for all four of the specified genes.

The subject matter of the invention is the analysis comprising selected gene parts of all four genes (APC, β -Catenin, B-raf, K-ras). The diagnosis of a colon carcinoma is effectively possible because alternatively mutated genes from the two intracellular pathways are detected. Since different types of colon cancer involve different pathways of cancerogenesis, one problem in the development of a method was to combine suitable markers detecting all types of colon carcinomas. The genes APC and p-Catenin are part of the Wnt-pathway, the genes K-ras and B-raf are part of the MAPK-pathway.

The selected combination of the above-mentioned four genes in combination with the claimed primers allows easy, reliable and effective diagnosis of colon cancer (see page 10 of the description).

Accordingly, Groups I-II are clearly linked by the same or a corresponding special technical feature as to form a single general inventive concept, unity of invention exists and applicant has met the requirements of PCT Rule 13.1.

Applicant respectfully requests favorable reconsideration of this restriction requirement.

Restriction

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Solely for the purpose of supplying a complete response,
applicant elect Group I, claims 1-6 and 11 and new claims 12-14.

Species Election

The examiner has identified the primers of SEQ ID NOS: 1-18
as distinct species and has required election.

Solely for the purpose of supplying a complete response,
applicant elects SEQ ID NO. 10.

Favorable reconsideration is respectfully requested.

The Commissioner is hereby authorized to charge payment for
any fees associated with this communication or credit any over
payment to Deposit Account No. 14-1263.

Respectfully submitted,

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